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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

SEP 10 2007

GROUP 3700

Application Number: 10/656,855
Filing Date: September 04, 2003
Appellant(s): RIVRON ET AL.

Jason Kelly
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/21/07 appealing from the Office action mailed 12/22/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: claim 38 remains only rejected under 35 U.S.C. 103.

New Grounds of rejection are also presented below.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,596,577	Sato	6-1986
6,352,555	Dzau et al.	3-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 11,12,14-17,19,20,22,33 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato (4596577). Sato discloses a vascular prosthesis that is a tube-shaped (Fig. 4) structure, col. 2, lines 65,66. Sato also describes the prosthesis is prepared using a mandrel (Gore patent), col. 3, lines 49-52. Sato discloses the luminal surface is rubbed with a brush having metal bristles (col. 3, lines 66,67) to lift nodes to some degree (see Fig. 3) to define a plurality of recesses or spaces there between the naps. Sato additionally discloses the material for the vascular prosthesis is expanded polytetrafluoroethylene, col. 3, lines 34-36. Sato discloses a luminal surface and abluminal surface can be rubbed and thus is within the tube structure, col. 4, lines 29-32. Sato also discloses both the luminal and abluminal surfaces can be rubbed and since it occurs along the luminal surface it can be said it is rubbed in a luminal direction, col. 4, lines 33,34. Since PTFE is known to be made up of interconnected nodes and fibrils, it must be inherent that when the fibrils are lifted the nodes are lifted.

Claims 19,23,24-30,32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzau et al. (6352555). Fig. 2 shows a vascular prosthesis (2) with a surface (6) including recesses (4) with cells **14** seeded thereon. Dzau et al. disclose the device is made of PTFE, col. 5, lines 11-13. Dzau discloses applying a frictional force

to pass the medium through the lumen or parallel to the axis of the vascular prosthesis to sod the cells on the surface, col. 5, lines 57-62. It is inherent that the force of the fluid causes the nodes to be lifted from the surface since recesses are formed as a result of passing over the surface and the cells adhered and filled them. Dzau et al. also disclose methods of harvesting cells for the prosthesis, col. 5, lines 19-33. Dzau et al. additionally disclose that the cells harvested are endothelial or precursors of endothelial cells, col. 3, lines 13-22. It is inherent that the cells would be seeded less than 15 minutes after harvesting or they would not be viable much longer.

Claims 18,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato '577. Sato is explained supra and as mentioned above does disclose both surfaces of the prosthesis can be rubbed. However, Sato fails to explicitly disclose the vascular prosthesis is everted after rubbing. The prosthesis is fully capable of being everted in the process of rubbing the other side after the first side is rubbed on the mandrel. It would have been an obvious matter of design choice to modify the position of the rubbed surface, since applicant has not disclosed that using an everted prosthesis provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rubbed prosthesis taught by Sato or the claimed everted prosthesis in claim(s) 18,38 because both prostheses perform the same function of providing recesses for cell ingrowth.

NEW GROUND(S) OF REJECTION

Claims 21,31,32,34,37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato (4596577). Sato does disclose rubbing a surface of a vascular prosthesis with a tool, col. 3, lines 64-67. Sato also discloses the formation of the nap with recesses there-between is done uniformly on the surface, col. 4, lines 28-31. However, Sato fails to explicitly disclose the brushing direction as "substantially parallel" to the orientation of the fibrils or "substantially perpendicular" to an orientation of the nodes. It would have been an obvious matter of design choice to modify the direction of the brushing disclosed by Sato, since applicant has not disclosed that rubbing in a direction parallel to the fibrils or perpendicular to the nodes provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rubbing direction taught by Sato or the claimed parallel rubbing in claim(s) 31, 32,34,37 or perpendicular to the nodes in claim 21 because both methods of rubbing perform the same function of providing recesses such that tissue ingrowth occurs to quickly stabilize the vascular prosthesis in place.

(10) Response to Argument

1) Applicant argues that Sato fails to teach as claim 11 recites that nodes are lifted from the surface and thus create a recess. As mentioned above, since it is known that PTFE is made up of interconnected nodes and fibrils that upon lifting of fibrils, the nodes must also inherently be lifted. Thus as a result, since the nodes are lifted as Applicant discloses a recess is made. Since the same material is disclosed by the prior

art and the same process of lifting nodes, the same result as claimed must be obtained. It is noted that in Applicant's argument (page 7) it is admitted that nodes could be lifted according to the Sato method, but does not state why they could not. It is the Examiner's position that because the microstructure of nodes and fibrils are interconnected they would be lifted to some degree upon the lifting of a fibril.

2) Applicant additionally argues that as claim 19 recites a force is applied to the device to lift nodes from the surface. As mentioned above, since the tool lifts the fibrils, it must also lift the nodes to some extent since the nodes and fibrils are interconnected. Applicant also argues that as recited in claim 33, that Sato does not disclose the device has nodes "substantially free of attached fibrils". However, after reviewing Applicant's specification, which defines a node free of fibrils as being "disrupted", the Examiner is of the position that Sato clearly discloses nodes that are free of attached fibrils since they are disrupted and partly torn, col. 4, lines 11-14.

3) Applicant argues that the limitations of claim 16 of rubbing in a luminal direction are not met by Sato. In response to applicant's argument that Sato fails to teach certain steps of applicant's invention, it is noted that the features upon which applicant relies (i.e., rubbing in some specific pattern) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, Sato does disclose the luminal surface is rubbed and thus it must be done in a luminal direction. The claims do not require any particular amount of rubbing to occur along the luminal surface, but just that rubbing

occurs along the luminal surface. Thus, since Sato discloses (col. 4, lines 31,32) the rubbing can be performed on its surface, it occurs in the luminal direction.

4) Applicant argues that Dzau does not disclose forming recesses as result of a frictional force of fluid passed over the surface of the device. The Examiner notes that according to Applicant's specification (paragraphs 7,8) the application of pressurized fluid to the surface will result in lifting nodes. Thus, since Dzau discloses the application of pressurized fluid to the luminal surface of the same material device as claimed by Applicant, it must inherently lift nodes just as Applicant discloses. The Examiner would also like to note that no hindsight or prima facie case of obviousness is established in a 102 (b) rejection, so Applicant's argument of the Examiner using hindsight construction or not establishing a prima case of anticipation is moot.

5) Applicant argues that the rejection of claims 18,38 over Sato is not obvious since a specific finding in the reference was not relied on for motivation. However, the Examiner noted that the surfaces of Sato's device both can be rubbed and thus while one of ordinary skill is working or rubbing one surface and then desires to rub the other clearly it can be pulled over the mandrel or in other words "everted". It is well known in the art that cellular responses immediately occur upon implantation of a foreign object in a patient and thus one of ordinary skill would desire to have rubbed the surfaces for providing a more biocompatible surface, which is easily accomplished on a mandrel by everting. Sato clearly teaches that by rubbing the surfaces it enhances the body response to become stable or secured in the patient, col. 4, lines 34-37.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Brian E. Pellegrino

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Conferees:

Corrine McDermott

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